

PROMISE III: Percutaneous Deep Vein Arterialization for the Treatment of Late-Stage Chronic Limb-Threatening Ischemia

NCT05313165

Status	RECRUITING
Phase	Not Applicable
Sponsor	LimFlow, Inc.
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (16)

- Subject must be between 18 and 95 years of age
- Clinical diagnosis of chronic limb-threatening ischemia, defined as any of the following clinical assessments: previous angiogram or hemodynamic evidence of severely diminished arterial inflow of the index limb (e.g., ABI \leq 0.39, TP / TcPO₂ \leq 30 mm Hg) and
- Rutherford Classification 5, ischemic ulceration or
- Rutherford Classification 6, ischemic gangrene
- Subject has been assessed by the Principal Investigator and determined that no conventional distal bypass, surgical or endovascular therapy for limb salvage is feasible due to either a) absence of a usable pedal artery target (endovascular or surgical approach), or b) the presence of a pedal artery target with absence of a viable single-segment vein in either lower extremity or either arm that could be used for autogenous vein conduit.

... and 11 more (see full listing online)

Exclusion (15)

- Concomitant hepatic insufficiency, thrombophlebitis in the target limb, or non-treatable coagulation disorder within the past 90 days.
- Active immunodeficiency disorder or currently receiving immunosuppressant therapy for an immunodeficiency disorder.
- Prior peripheral arterial bypass procedure above or below the knee which would inhibit proximal inflow to the stent graft.
- Absence of adequate viable tissue in target foot.
- Life expectancy less than 12 months.

... and 10 more (see full listing online)

Locations (30 total)

University of California, San Diego Health, La Jolla, California, United States
Stanford University School of Medicine, Palo Alto, California, United States
UCSF, San Francisco, California, United States

... and 27 more locations